TALC

Containing no asbestos fibers

CAS: 14807-96-6

TLV–TWA, 2 mg/m^3, Respirable dust

Containing asbestos fibers

TLV–TWA, Use asbestos TLVs; however, should not exceed 2 mg/m^3 respirable dust

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Containing no asbestos fibers with < 1% crystalline silica

1946–1947: MAC–TWA, 20 mppcf

1948–1969: TLV–TWA, 20 mppcf

1970–1982: TLV–TWA, 20 mppcf, nonasbestiform

1980: TLV–TWA, 15 mppcf or 2 mg/m^3, respirable dust; proposed

1983–present: TLV–TWA, 2 mg/m^3, respirable dust

Containing asbestos fibers

1970–1984: TLV–TWA, use asbestos limit

1978: TLV–TWA, 0.5 fiber/cc, proposed

1980: TLV–TWA, 2 fibers/cc, > 5 μm in length; proposed

1983: TLV–TWA, use asbestos TLV–TWA, however, should not exceed 2 mg/m^3 respirable dust; proposed

1985–present: TLV–TWA, use asbestos TLV–TWA, however, should not exceed 2 mg/m^3 respirable dust

1992: Documentation revised

Chemical and Physical Properties

Talc is a mineral product, the composition of which varies widely from one geological deposit to another and even within the same deposit. The main component is a crystalline hydrated silicate of magnesium that is usually in the form of plates but rarely may also be in the form of fibers. In many talc deposits, other silicates such as tremolite and anthophyllite (both of which are amphiboles) and serpentines in the form of antigorite, lizardite, and even chrysotile may be present. Varying small amounts of other mineral ore are also encountered frequently in the products used as talc. However, there are deposits that consist almost entirely of platiform talc crystals without significant admixture by other types of crystals or materials.[1] The melting range of talc is between 900° and 1000°C.[2] Talc is insoluble in water, cold acids, and alkalies.[3]

Major Uses or Sources of Occupational Exposure

Talc is used extensively in industrial products as well as in cosmetics. Only the relatively pure platiform talc is used in cosmetics. About 1,000,000 tons of talc were produced in the United States in 1983. The following products contain talc: ceramics, paints, cosmetics, paper, plastics, rubber, roofing, insecticides, and refractory.[1] In the National Occupational Exposure Survey (NOES) performed during 1981 to 1983, the National Institute for Occupational Safety and Health (NIOSH) estimated that 4245 employees were exposed to talc.[4]

Animal Studies

Chronic/Carcinogenicity

Experimental investigations of the biologic effects of talc and tremolite have been reported from several laboratories. Wagner et al.[5] studied Italian talc that consisted of 92% talc mineral, 3% chlorite, 1% carbonate, and 0.5% to 1.0% quartz. The sample contained no asbestos or tremolite. Less than 2% of the particles were fibrous. Many of the fibrous particles were laths of talc or chlorite mineral. Rats were injected intrapleurally with 20 mg of this talc, no mesotheliomas developed. Other rats were fed 100 mg talc/day/rat. All animals were allowed to live out their lives. The only abnormality in the gastrointestinal tract was a gastric leiomyosarcoma in one rat. Two groups of 24 male and female Wistar-derived rats, 12 of each sex per group, were exposed to the Italian talc for 6 or 12 months at a 10.8 mg/m^3 concentration, 7.5 hours/day, 5 days/week.[5] A like number of male and female control rats received no talc exposures. Ten days after termination of the last exposures, six rats from each group were sacrificed; 12 months later, an additional four rats from each group were sacrificed. An additional 12 animals in each exposure group died within 28 months of the initiation of exposures. No lung tumors were observed in any of the rats exposed for 6 months; one lung adenoma was found among the animals exposed for 12 months. No lung tumors were found in any of the controls. "Minimal to slight" fibrosis was recorded for the 1-year-exposed rats, the degree of which increased to "moderate" within 1 year after termination of exposures.

Wehner et al.[6] investigated the pulmonary effects of talc baby powder in hamsters. Groups of 100 animals were exposed to dust concentrations of 9.8 and 8.1 mg/m^3 for totals of 1.5 hours, 15 hours, and 75 hours over a 30-day period and another two groups of 100 hamsters were exposed for 30 or 150 minutes/day for 300 days, unless they died sooner. About 20% of the particles inhaled by the latter two groups of hamsters had an aerodynamic equivalent diameter of < 3 μm. The animals were allowed to live out their lives. No significant lesion attributable to the exposure was found. However, the authors stated,[6] "It is possible that markedly higher exposure levels would have caused talcosis eventually."

The ability of asbestiform tremolite and tremolitic talc to cause pleural cancers in hamsters was investigated by Smith et al.[7] Four different dusts were studied:

No. 72: An asbestiform tremolite consisted of 95% tremolite and contained long thin fibers with parallel sides, having an average diameter of 0.4 μm. Many fibers were > 20 μm long.

No. 31: Obtained from a tremolitic talc in the western United States and consisted of 90% tremolite. Some particles had parallel sides. Many of the particles resembled acicular fragments rather than fibers. The average diameter was 0.5 μm.

No. 275: Consisted of 95% tremolite and contained some fiber-shaped particles with parallel sides and roughly shaped acicular fragments. There was a paucity of long thin particles. The average diameter was 0.4 μm.

FD 14: Consisted of 50% tremolite, 35% talc, 10% antigorite, and 5% chlorite. There were platy and amorphous particles as well as long thick and thin fibers. The average diameter was 1.6 μm.

These dusts were injected intrapleurally into groups of hamsters in doses of 25 mg or 10 mg. No tumors were produced by the FD 14 dust at the 25-mg dose level or by No. 275 at either the 25-mg or the 10-mg doses. Both No. 31 and No. 72 dusts caused pleural cancers. However, fewer animals with cancer were seen in the group injected with No. 31 than in the group injected with No. 72. The investigators[7] concluded that the nonasbestos form of tremolite was not carcinogenic, whereas the asbestos type of tremolite was carcinogenic.

In a 1992 draft report, the National Toxicology Program (NTP)[8] reported the results of toxicology and carcinogenesis studies of nonasbestiform (cosmetic grade) talc in rats and mice by the inhalation route. The conclusions of these studies were approved at a peer review meeting in June of 1992. Groups of rats and mice of both sexes were exposed to aerosols containing 0, 6, or 18 mg/m^3 talc for up to 113 weeks (male rats), 122 weeks (female rats), and 104 weeks (mice). Based on an increased incidence of benign and malignant pheochromocytomas of the adrenal gland in the male rats, NTP concluded that there was "some evidence of carcinogenic activity" of talc in male rats. Based on increased incidences of alveolar/broncheolar adenomas and carcinomas of the lung and benign and malignant pheochromocytomas of the adrenal glands in the female rats, NTP concluded that there was "clear evidence of carcinogenic activity" of talc in female rats. Exposure of the mice to talc was associated with chronic active inflammation and the accumulation of macrophages in the lung. In contrast to the rats, hyperplasia of the alveolar epithelium, squamous metaplasia, or interstitial fibrosis were not associated with the inflammatory response in mice and the incidences of pulmonary neoplasms in exposed and control groups of mice were similar. Accumulation of macrophages (histiocytes) containing talc particles were also present in the bronchial lymph nodes. Based on these results, NTP concluded that there was "no evidence of carcinogenic activity" of talc in male or female mice.

Reproductive/Developmental

In addition to the ingestion study conducted by Wagner et al.,[5] two other investigations have been concerned with the ingestion of talc.[9,10] The purpose of the latter was to evaluate the teratologic potential of a talc product of undisclosed composition. Rabbits and mice were given large doses of this talc for 13 and 10 successive days, respectively. The results were completely negative.

Human Studies

Past epidemiologic studies on the health aspects of mining and milling talc have been reviewed by Dement et al.[11] and only the more recent studies of larger cohorts of talc workers as well as experimental investigations will be considered in detail for the purposes of this documentation. As reviewed by Dement et al.,[11] most reports are concerned with talc mines in New York State and most of them produced talc containing varying amounts of tremolite and anthophyllite. Some talcs were said to also contain serpentines and silica. The number of men involved in the different studies ranged from 6 to 221. Their dust exposure ranged from near zero to over 800 mppcf, generally higher for millers than miners. With the introduction of wet drilling and other engineering improvements in 1945, the dust exposures generally decreased significantly. However, because of the previous high dust exposures, all of the reports indicated significant deterioration of the health of the workers commensurate with the severity and duration of the exposure. These health effects pertained to the respiratory system and consisted of cough, dyspnea, wheezes, rales, infiltrations in the chest X-ray films, and abnormal lung function tests.

The retrospective cohort mortality study reported by Dement et al.[11] is based on 398 white male workers who began employment between January 1, 1947 and December 31, 1959 and whose vital status was determined as of June 30, 1975. Of these, 74 were known to be dead. Bronchogenic cancer was the cause of death in 9 men, whereas only 3.3 deaths had been expected. Nonmalignant respiratory disease (NMRD) exclusive of influenza, pneumonia, and tuberculosis caused 3 deaths, whereas 1.5 had been expected. From these data, the authors concluded that there was a significant increase in mortality due to bronchogenic cancer and NMRD from occupational exposure to talc dust.

The report[11] included a morbidity study of 121 current workers that was based on questionnaires, lung function tests, and chest X-rays. From these it was concluded that there was a higher prevalence of cough, phlegm, dyspnea, and irregular opacities in the chest X-ray films than in potash miners. Pleural thickening and calcification was found to be significantly higher in talc workers than in coal and potash miners. Pulmonary function of talc workers was reduced compared to that of coal and potash miners who had worked an equal num-

ber of years. Reductions in forced expiratory volume (FEV) and forced vital capacity (FVC) correlated with years worked and dust exposure.

The authors[11] estimated the total dust exposure in terms of mg-years/m^3 and the total fiber exposure in terms of fiber-years/cc on the basis of results of personal sampling conducted in 1975 multiplied by the number of years spent at that job. However, data presented by the investigators[11] indicates that there was a nearly 900% reduction in dust count (all operations) in 1975 in the mines from the highest count in 1968 and approximately an 800% reduction in dust count in 1975 from the highest count in 1958 in mill operations. This alone makes any attempt to correlate the estimates of dust exposure based on the 1975 dust determinations with the impairment of lung function, chest X-ray film abnormalities, or symptoms valueless and misleading. Added to these deficiencies is the failure of the authors[11] to exclude from the 121 participants in the morbidity study, those men whose previous employment had been in other dusty trades or was unknown. The probability that a significant number of such men in these categories may have been included in this study is suggested by data in which 16 of the 19 workers listed had either worked in other dusty trades or their previous employment was unknown.

The dust exposures of the talc workers consisted of fibrous and nonfibrous particles. More than 90% of the total airborne particles were said to have been < 5 μm long. Of the fibers longer than 5 μm, 65% were anthophyllite, 7% were tremolite, and 25% were not positively identified, although many of the latter had X-ray spectra identical to tremolite.

In contrast to these findings is a report of Campbell[12] on the examination of three air filter samples from the same mine:

> Few particles observed were identified as asbestiform minerals. No asbestiform particles were observed in sample JW-18, although a few alteration products could be confused with asbestos. In sample MP-9 two particles (0.6%) could possibly be amphibole asbestos. In sample RB-86 approximately 8 (2%) particles are possibly asbestiform amphiboles. The rest of the amphibole particles (tremolite and anthophyllite) counted in all samples were cleavage fragments.

It should be noted that 350 particles were counted in each sample.

The conclusions of excessive risk of death from lung cancer and NMRD among talc workers in the above cohort was questioned by Lamm and Tabershaw.[13] Using the same personnel records used in the NIOSH report,[11] they classified each employee on the basis of previous mineral dust exposure:

1. Definite prior mineral dust exposure — 218 men
2. Probable prior mineral dust exposure — 20 men
3. No known prior mineral dust exposure — 134 men

Lamm and Tabershaw stated:[13]

> When standardized mortality rates were calculated for these three subcohorts, it was seen that there was no excess mortality from respiratory cancer or NMRD in those workers whose only known mineral exposure was at this mine. Those excesses that were observable were only in the subcohorts with definite or probable prior mineral dust exposure.

In a follow-up study of 220 talc workers by Kleinfeld et al.[14] in a New York State mine producing talc containing tremolite and anthophyllite, 91 deaths were investigated. Of these 91 deaths, 9 were caused by lung cancer, 1 by pleural sarcoma, and 28 by pneumoconiosis or its complications or both. All 28 deaths ascribed to pneumoconiosis and the 10 respiratory cancer deaths occurred in men who had had their initial exposure prior to the institution of wet mining and other effective engineering controls in 1945. The proportional mortality from cancer of the lung and pleura was four times that of the control population. The authors[14] state, "In the absence of adequate smoking data one cannot assess the role played by smoking in the causation of the pulmonary carcinomas in both series" (talc and asbestos).

The same cohort was restudied and reported in 1974.[15] It now was composed of 260 talc workers with 108 deaths. There were 13 cancers of the lung and pleura and 29 deaths from pneumoconiosis and complications. Table 1 shows the distribution of deaths for the 12 lung cancers and 1 pleural sarcoma, and of pneumoconiosis and complications according to 5-year periods during which they occurred.

TABLE 1. Distribution of Deaths According to Years of Occurrence

Year	Cancer of Lung and Pleura	Pneumoconiosis and Complications
1940–44	—	2
1945–49	2	4
1950–54	1	2
1955–59	5	8
1960–64	3	9
1965–69	2	4
Total	13	29

The differences between observed and expected mortality rates were stated to have been significant in 1950 to 1954 ($P < 0.01$) but not significant in 1960 to 1964 and 1965 to 1969 ($P > 0.05$). This may be related to the

TABLE 2. Dust Counts in mppcf

Years	Range of Averages
Pre–1945	120–818
Pre–1948	69–1227
1948–1965	25–73
1966–1969	9–43

reduction of the dust counts as shown in Table 2.

The dust exposure was predominantly to talc, tremolite, anthophyllite, carbonates, and small amounts of silica. The percentage of deaths due to pneumoconiosis and complications, according to the authors[15] had decreased by more than 50% in the last 5-year period (1965–1969). Fiber counts made in 1972 showed a range of averages from 3/ml to 36/ml > 5 μm in length. In another mine studied by Kleinfeld et al. (1973) and quoted in their 1974[15] paper, controls had been installed at the inception of operations in 1948. Only 1 of 39 workers had chest X-ray changes consistent with pneumoconiosis. This was a 75-year-old man who had worked as a janitor for 11 years. Because of the lack of X-ray evidence of pneumoconiosis in this cohort despite a fiber count that was 2 to 6 times the TLV of 5 fibers/ml > 5 μm and a mean exposure of 16.2 years with a range of 11 to 22 years, Kleinfeld et al.[15] concluded that tremolite and anthophyllite were less fibrogenic than chrysotile and amosite at comparable dust exposures. It is reasonable to presume that the tremolite and anthophyllite in the talc were in the usual prismatic, acicular, or fibrous habit and rarely present as asbestos.

When the past and recent reports on the health effects of amphibole-containing talc on mine and mill workers are viewed in perspective, there remains no doubt but that serious health problems had developed from this kind of dust at exposure levels as were commonly encountered prior to 1945. The data also indicate that with the introduction of wet mining and other engineering improvements, the excess of death rates from pneumoconiosis and lung cancer has all but disappeared concomitant with the reduction in dust concentration.

Two reports are identified on the health of workers mining and milling a talc of high purity. The report of Rubino et al.[16] is concerned with 1514 miners and 478 millers. The average exposure levels of the miners ranged from 849 to 8470 mppcf-years and that of the millers, from 76 to 651 mppcf-years. There were 704 deaths among the miners (791.2 expected) and 227 deaths among the millers (258.4 expected). There was no relationship between the ratio of observed to expected deaths and the interval between first exposure and death. There was an excess of deaths from silicosis over the expected. This excess was greater among miners than millers. Associated with silicosis there were also excessive deaths from silicotuberculosis. The authors concluded,[16]

> The trend of mortality from respiratory diseases in relation with dose and latency and the different incidence of silicosis respectively in miners and millers, allows us to assume that the inducing factor is silica rather than talc.

The silica content of the dust in the mines ranged from 14% to 18%, whereas that in the mills ranged from < 1% to 2%. The fiber counts in both, mills and mines, ranged from not measurable to 0.01 fiber/ml > 5 μm in length.

Another study of miners and millers of nonasbestos talc[17] involves 90 deaths in a cohort of 392 workers in Vermont mines, employees of five companies. Mortality patterns were assessed from January 1, 1940 through December 31, 1975. Among the millers, two respiratory cancers were observed and 1.96 had been expected. The ratio of observed to expected deaths from NMRD exclusive of influenza and pneumonia among the millers was 7:0.89 ($P < 0.01$). Among the miners, this ratio for respiratory cancer was 5:1.15 ($P > 0.05$) and it was 2:0.59 for NMRD.

The causes for the excess in cancer deaths among the miners and the NMRD deaths among the millers has not been determined. The study is obviously incomplete because the authors[17] state,

> NIOSH is currently attempting to identify any possibly confounding workplace exposures that may have occurred prior to or after employment in the Vermont talc industry for those who died from malignant or nonmalignant respiratory disease . . .

also,

> The fact that excess lung cancer mortality was observed for miners and not millers, despite probable higher dust exposure in mill operations, suggests that additional etiologic agent(s), either alone or in combination with talc dust, affect mine workers. The possible role of radon daughters for this cancer mortality risk cannot be eliminated.

TLV Recommendation

Most of the reports dealing with the health effects of talc are concerned with those talcs that contain, in addition to platiform talc crystals, appreciable amounts of amphiboles and other minerals. The health problems appear to evolve predominantly from the nonplatiform content of the talc being mined and milled. There is considerable controversy regarding the extent to which the nonplatiform constituents are asbestos. In this context the terms asbestos and asbestiform are often used

interchangeably. This has been extended, particularly by regulating agencies to include nonasbestos minerals that exist in fiber form — a fiber being defined as a particle that is 3 or more times longer than its width. This controversy has been summarized by Campbell et al.[18] of the U.S. Bureau of Mines as follows:

> Now there is increasing concern regarding the effects on industrial employees and the general public from long-term, low level and short-term high level exposure to various elongate mineral particulates present as minor or major constituents in ores, crushed stone, and various industrial minerals. These particulates include both the more common and the asbestos varieties of serpentine and amphibole minerals . . .

These authors continue,

> While it is correct that all asbestos minerals are fibrous, not all minerals having a fibrous habit are asbestos . . . and . . . The term fibrous is used in a general mineralogical way to describe any aggregates of grains that crystallize in a needlelike habit and appear to be composed of fibers . . .

According to Campbell et al.,[18] fibrous minerals include those with a crystallization habit ranging from prismatic, acicular, and fibrous to asbestos. The asbestos minerals of commercial importance have the following characteristics:

1. Aspect ratios ranging from 1000:1 or higher
2. Very thin fibrils, generally less than 0.5 μm in width
3. Very high flexibility and tensile strength compared tononasbestos minerals
4. Parallel fiber growth in veins.

Because of known severe health effects associated with excessive exposures to asbestos, regulatory agencies tend to regard all elongate mineral crystal particles, whether prismatic acicular, or fibrous as asbestos — the only provision being that the particles have an aspect ratio of 3:1 or greater. Consideration is given to their respirability, i.e., their width being 3 μm or less. In this connection, the statement of Zoltai and Stout[19] is pertinent:

> Unfortunately, the misuse of some relevant mineralogical concepts and terms are becoming so widespread that it may be difficult to correct them. However, if that is not done, some mineralogical concepts and expressions will have double definitions: one for mineralogists and physical scientists, and one for the use in environmental public health sciences and practices. The continuing use of these double definitions would be most unfortunate as it will undoubtedly lead to additional misunderstanding and conflict between mineralogists and geologists on one side, and environmental and public health personnel on the other. As the concepts and expressions are mineralogical, the logical solution to this problem would be for personnel in the second category to restrict themselves to the proper use of mineralogical terms."

No data on the health effects of elongate mineral particles having prismatic, acicular, or fibrous (nonasbestos) habits of amphiboles, serpentines, or talc are available except from some limited experimental data on tremolite. Campbell et al.[18] point out that experimental evidence indicates that the carcinogenic potential of mineral fibers is related to the size class with a diameter of < 0.25 μm and a length > 8 μm and that shorter and thicker particles were not as biologically active.

There is little question but that the dust of nonfibrous talc, consisting almost entirely of platiform talc crystals and containing no asbestos, carries a relatively small respiratory hazard that must be controlled. The degree to which controls should be applied to talc dust should depend upon its asbestos content. However, difficulties arise in attempting to differentiate between cleavage fragments of prismatic or acicular habit, nonasbestos fibers, and asbestos fibers. Although experimental evidence indicates that carcinogenicity is associated with thin, long fibers, i.e., fibers < 0.5 μm wide and > 8 μm long, more than 90% of the fibers counted by Dement et al.[11] in the dust to which the talc miners were exposed were < 5 μm long. It appears that most of the fibers that are counted in talc dust, i.e., particles with an aspect ratio > 3:1 and > 5 μm long are not asbestos. This was indicated by the report of Campbell[12] on a fibrous talc in which only 0.6% and 2%, respectively, of 350 particles in each of two samples could be identified as asbestos, and no asbestos could be identified in 350 particles of a third sample.

A further indication of the probability that only few of the fibers in fiber-containing talc are asbestos — even though they may definitely be tremolite or anthophyllite in a nonasbestos crystal habit — is suggested by the findings of Kleinfeld et al.[15] With the exception of the chest X-ray of a 75-year-old man who had worked as a janitor for 11 years and whose pre-employment X-ray was positive for pneumoconiosis, these investigators could find no X-ray changes consistent with pneumoconiosis in the chest X-ray films of talc workers exposed to 10 to 30 fibers/cc > 5 μm for a mean of 16.2 years with a range of 11 to 22 years. This finding suggested to Kleinfield et al.[15] that tremolite and anthophyllite were less fibrogenic than chrysotile and amosite.

As previously indicated, the talc mined and used industrially generally also contains amphiboles and serpentines, as well as other minerals in the form of acicular, prismatic, and fibrous (different from asbestos) crystals that may have aspect ratios equal to or greater than 3:1

and, therefore, qualify as "fibers." The health effects of these crystals is presently unknown. Asbestos fibers contained in talc dust must, however, be limited in the ambient air so that their established TLV is not exceeded.

Supported by the above data, the following recommendations are made: for talc containing no asbestos fibers with < 1% crystalline silica, a TLV–TWA of 2 mg/m^3, respirable dust; for talc containing asbestos fibers, use the TLV–TWA for asbestos, however, exposures should not exceed 2 mg/m^3 respirable dust.

Other Recommendations

OSHA PEL: OSHA established a PEL–TWA of 2 mg/m^3 for the respirable dust of talc containing no asbestos fibers and less than 1% crystalline silica. OSHA concluded that this limit would protect workers from the significant risk of nonmalignant respiratory effects associated with exposure to talc dust. OSHA has not made any determinations with regard to the possible health consequence resulting from exposure to talc fibers. OSHA uses the asbestos standard (29 CFR 1910.1001) for talc (containing asbestos).[20] The OSHA PEL is consistent with the recommended ACGIH TLV with the exception of differing exposure limits for asbestos.

NIOSH REL/IDLH: NIOSH [Ex 8-47, Table N1] established a REL–TWA of 2 mg/m^3 for the respirable dust of talc containing no asbestos fibers and less than 1% crystalline silica by concurrence with the OSHA PEL.[20] NIOSH has not established an IDLH value for this substance, because no evidence could be found for the existence of an IDLH value.

For talc containing asbestos, NIOSH recommended using the REL for asbestos.[21]

NTP Studies: NTP conducted a chronic inhalation study of talc at 0, 6, and 18 mg/m^3; this study has been peer reviewed in June 1992. There was some evidence for carcinogenicity of talc in male rats, clear evidence in female rats, and no evidence in male and female mice.

Carcinogenic Classification

Talc not containing asbestos fibers

IARC: Group 3, not classifiable as to its carcinogenicity to humans.

Talc containing asbestos fibers

IARC: Group 1, carcinogenic to humans.
MAK: Group A1, unequivocally proven carcinogenic.
NIOSH: Carcinogen, with no further categorization.
NTP: Group 1, sufficient evidence of carcinogenicity from studies in humans.
OSHA: Carcinogen, with no further categorization.
TLV: A1, confirmed human carcinogen.

Other Nations

Australia: containing no asbestos fibers 2.5 mg/m^3, inspirable dust (substance under review) (1990); Federal Republic of Germany: without asbestos fibers 2 mg/m^3, fine dust (1992); United Kingdom: 10 mg/m^3, total inhalable dust, 1 mg/m^3, respirable dust (1991).

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